

**Remarks**

Claims 2-69 are pending in this application. In the present Response, Claims 64 and 67 have been canceled. Claims 14 and 16 have been amended to change the dependency from claim 1 to claim 2; and claim 28 has been amended to change the dependency from 19 to 18.

Each of the rejections is addressed individually.

**Rejection of claims 2-33 and 49-63 under 35 USC 103**

The Examiner has rejected these claims as being unpatentable over Horowitz (U.S. patent no. 4,613,501), and Barbour et al. (U.S. patent no. 5,777,095).

**Rejection over Horowitz**

The Examiner contends that Horowitz teaches inactivation of purified microorganism by formaldehyde or glutaraldehyde. However, it is respectfully pointed out that claim 2 of the present invention recites a purified microorganism in which one or more surface proteins have been irreversibly modified by covalent attachment so as to render the microorganism to be non-pathogenic and in which the nucleic acids are substantially intact. In Horowitz, the blood borne viruses are described as being contacted with aldehydes (col. 1, lines 25-40). There is no teaching of purification of the viruses and further, there is no indication that the nucleic acids are substantially intact.

**Rejection over Barbour**

Although Barbour teaches a non-pathogenic microorganism, this is to be used as a live vaccine for the immunization of an animal (col. 19, line 25). There is no teaching of modification of surface proteins by covalent attachment. On the contrary, to preserve the immunogenicity, one skilled in the art would not expect to have modification of surface proteins. Further, there is also no teaching or even consideration regarding keeping the nucleic acids intact so as to render them amenable to amplification.

**Rejection of claims 49-63 over Horowitz and Barbour in view of Andrieu**

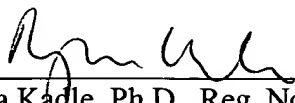
The references of Horowitz and Barbour have been discussed above. Andrieu discloses a using viruses obtained from cultures of cells infected with the virus. These viral particles are not purified as in the present invention. Further, there is no covalent modification of the surface proteins to render the microorganism non-pathogenic. Thus, Andrieu does not disclose the positive control composition of the present invention in which one or more surface proteins in the microorganism are irreversibly modified to render the microorganism non-pathogenic and in which the nuclear components are substantially intact. Accordingly, Applicants submit that there is no teaching or suggestion in these three references, either individually or combined to obtain a kit comprising a positive control composition as recited in claims 49-63. The Examiner is therefore respectfully requested to withdraw this rejection.

### **Conclusion**

Applicants note that claims 34-48 and claims 64-69 were deemed to be allowable. However, based on the amendments and arguments presented herein, Applicants believe that all pending claims, i.e., claims 2-63, 65, 66, 68 and 69 are now in a condition for allowance and therefore respectfully request the Examiner to allow these claims.

A fee of \$120 is enclosed for a one-month extension. If any additional fee is due, it may be charged to Deposit Account No. 08-2442.

Respectfully submitted,  
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